UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE NATIONAL PRESCRIPTION OPIATE LITIGATION	MDL No. 2804
This document relates to: *Track One Cases*	Case No. 17-md-2804
	Hon. Dan Aaron Polster

GENERIC MANUFACTURERS' MEMORANDUM IN SUPPORT OF MOTION FOR PARTIAL SUMMARY JUDGMENT

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I. INTRODUCTION

Generic Manufacturers[1] make a wide variety of affordable medicines to treat debilitating diseases, such as multiple sclerosis, cancer, and Parkinson's disease, along with opioids to treat debilitating pain. What Generic Manufacturers indisputably do not do is promote the safety and efficacy of any of their generic medicines. ***Plaintiffs' own experts*** have confirmed that "brand companies"—not generic manufacturers—"are primarily the ones that engage in marketing,"[2] and that "[g]enerally, manufacturers will not detail physicians for generics," because "physicians are not generally making a decision about one generic versus the other."[3]

Plaintiffs' claims against Generic Manufacturers, however, rest in large part on the theory that they falsely promoted the safety and efficacy of their generic opioid medicines to prescribers.[4] But if there is no promotion, there can be no false promotion, and if there is no false promotion, no claims stand based on a false marketing theory. After hundreds of fact and expert depositions, the undisputed facts confirm that Generic Manufacturers have never engaged in the type of promotion that forms the basis for Plaintiffs' claims with respect to any generic products. Nor have Plaintiffs (or any of their experts) identified a single false statement by any Generic

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[1] "Generic Manufacturers" include Actavis Pharma, Actavis LLC, Watson, Warner Chilcott Company, LLC, Actavis South Atlantic LLC, Actavis Elizabeth LLC, Actavis Mid Atlantic LLC, Actavis Totowa LLC, Actavis Kadian LLC, Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City, and Actavis Laboratories FL, Inc., f/k/a Watson Laboratories, Inc.-Florida (collectively, "Actavis Generic Defendants"); Endo Pharmaceuticals Inc. and Endo Health Solutions Inc. (collectively, "Endo Defendants"); Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (misnamed as "Par Pharmaceutical Companies, Inc. f/k/a Par Pharmaceutical Holdings, Inc.") (collectively, "Par Defendants"); Teva Pharmaceuticals USA, Inc. ("Teva USA"); and the generics business of Mallinckrodt LLC and SpecGx LLC (together, "Mallinckrodt"). As to the Endo Defendants, Teva USA, Mallinckrodt LLC, and SpecGx LLC, Generic Manufacturers move for partial summary judgment with respect to all false marketing claims brought only as to their generic medicines. Mallinckrodt plc is an Irish company that is not subject to and contests personal jurisdiction for the reasons explained in its pending motion to dismiss for lack of personal jurisdiction; it is specially appearing to join this motion as a result of the Court's deadline to file dispositive and *Daubert* motions, and, thus, it does not waive and expressly preserves its pending personal jurisdiction challenge. Lastly, though Noramco, Inc. ("Noramco") is an active pharmaceutical ingredient supplier and not a finished drug product manufacturer, like the Generic Manufacturers, Noramco does not market or promote finished drug products. Thus, it joins Section III(A).

[2] Ex. 1 (Deposition of Meredith Rosenthal), at 197:23–198:4.

[3] *Id.*

[4] *See* Summit Third Amended Complaint ("TAC"), ECF No. 1466, at ¶¶ 9–12; Cuyahoga Third Amended Complaint ("TAC"), ECF No. 1631, at ¶¶ 9–12.

Manufacturer to any Ohio prescriber about any generic opioid medicine, much less one that caused that prescriber to write a harmful prescription. No such evidence exists.

The lack of promotion by Generic Manufacturers stems from public policy implemented by the Hatch-Waxman Amendments to the Food Drug and Cosmetics Act ("FDCA"). Congress amended the FDCA to allow for greater availability of generic medicines, and, thus, for "the American people [to] save money" and "receive the best medicine that pharmaceutical science can provide." *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1568 (Fed. Cir. 1997) (citations omitted). As courts recognize, generic manufacturers "compete on price and ***avoid marketing to physicians*** because the costs of such marketing severely impact their ability to offer the significantly lower prices upon which they compete." *New York ex rel. Schneiderman v. Actavis, PLC*, No. 14-cv-7473, 2014 WL 7015198, at *27 (S.D.N.Y. 2014), *aff'd*, 787 F.3d 638 (2d Cir. 2015) (emphasis added). Promoting the safety and efficacy of generic medicines also makes little sense because a pharmacy—not a physician—makes the decision whether to substitute a generic medicine for a brand medicine only after a physician writes a prescription. *Id.*

Additionally, Plaintiffs cannot bring these false marketing claims based upon a failure-to-disclose theory because such claims are preempted as a matter of controlling law. The hallmark of the Hatch-Waxman Act is a duty of sameness, thus prohibiting a generic manufacturer from changing the design of a generic medicine, altering its FDA-approved labeling, or issuing additional warnings. *See* 21 U.S.C. § 355(j)(2)(A). Applying this "sameness" requirement, the Supreme Court and the Sixth Circuit have held that state law claims requiring generic manufacturers to communicate information beyond their FDA-approved labels are preempted regardless of how they are framed.[5] Consistent with this controlling case law, this Court adopted

[5] *See Mut. Phar. Co., v. Bartlett*, 570 U.S. 472, 490 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011); *McDaniel v. Upshur-Smith Labs., Inc.*, 893 F.3d 941, 945–47 (6th Cir. 2018); *In re Darvocet, Darvon, &*

the Report and Recommendation ("R&R") in the *Blackfeet* and *Muscogee* ("Tribal") cases, which recommended that failure-to-disclose claims against generic opioid manufacturers be dismissed because they are preempted.[6]

Lastly, Plaintiffs cannot argue that Generic Manufacturers are liable because they sold generic prescription medicines in a market purportedly created by alleged false marketing of brand name prescription medicines by other companies. At bottom, this is a theory that Generic Manufacturers should have stopped selling their FDA-approved medicines because of other companies' marketing practices. This theory would impose liability for ***complying with*** FDA rules and regulations and would improperly force Generic Manufacturers to cease federally-lawful conduct. For these reasons, the Supreme Court and the Sixth Circuit have rejected this "stop-selling" theory as "incompatible with our pre-emption jurisprudence" and "incoheren[t]." *Bartlett*, 570 U.S. at 488; *see also In re Darvocet*, 756 F.3d at 925.

II. THE UNDISPUTED FACTS SHOW THAT GENERIC MANUFACTURERS DID NOT PROMOTE THE SAFETY AND EFFICACY OF THEIR MEDICINES.

A. Generic Manufacturers Operate Differently Than Brand Manufactures And Do Not Promote The Safety Or Efficacy Of Generic Medicines To Physicians.

The FDCA enables generic medicines to obtain FDA approval by showing equivalence to a brand-name medicine ***already approved*** by the FDA. *Mensing*, 564 U.S. at 612. Generic medicines enter the market only when the brand-name equivalent medicines lose their patent protection,[7] and, as a result, face stiff competition and "cost less than their brand-named

Propoxyphene Prods. Liab. Litig., 756 F.3d 917, 935–36 (6th Cir. 2014); *Strayhorn v. Wyeth Pharma.*, 737 F.3d 378, 391 (6th Cir. 2014); *Brinkley v. Pfizer, Inc.*, 772 F.3d 1133, 1139 (8th Cir. 2014); *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 612 (5th Cir. 2014); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 475 (5th Cir. 2014) (per curiam); *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249 (11th Cir. 2013); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1286 (10th Cir. 2013).

[6] *See Muscogee*, 1:18-op-45459, ECF. No. 104 at 42, Report and Recommendation; *Blackfeet*, 1:18-op-45749, ECF. No. 56 at 15, Report and Recommendation; *In Re National Prescription Opiate Litigation*, 1:17-md-02804, ECF No. 1680, Order (adopting relevant portions of R&R).

[7] Ex. 21, at p. 3.

counterparts."[8] The FDA explains that manufacturers of generic medicines "generally do not pay for advertising, marketing and promotion," which allows them to be "substantially less expensive than brand-name drugs."[9] Likewise, the FTC has acknowledged that "[b]rand-name drugs are marketed by emphasizing product differentiation to physicians and consumers . . . . By contrast, generic drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."[10]

In addition, under Ohio's drug substitution laws, a pharmacy dispenses a generic opioid medicine only after a prescriber first chooses to write a prescription for his or her patient for a branded drug; the pharmacist then substitutes the less expensive generic medicine for the more expensive branded product. *See* Ohio Rev. Code § 4729.38 (Ohio's drug substitution laws); *id.* § 3715.01 (Ohio's definition of generically equivalent drug). Because a prescriber has no control over which Generic Manufacturer's medicine is substituted for the more expensive brand-name medicine at the pharmacy, Generic Manufacturers do not market the safety and efficacy of their medicines to prescribers. *See Actavis, PLC*, 2014 WL 7015198, at *27 (discussing principle).

B. Generic Manufacturers Are Bound by The Duty of Sameness And Are Limited In What They Can Communicate To Physicians.

The FDCA requires generic medicines to be the same as their branded equivalent in every clinically significant way, including with respect to labeling. 21 U.S.C. § 355(j)(2)(A).[11] This is known as the "sameness" requirement.

Because of the sameness requirement, generic manufacturers are limited in what they can communicate to physicians. The Supreme Court and the Sixth Circuit have held that the sameness

[8] *Id.*
[9] Ex. 2, at p. 1.
[10] Ex. 3, at p. 17.
[11] As the Sixth Circuit has recognized, "advertising and promotional materials are considered labeling" under FDA regulations applicable to generic manufacturers. *See Strayhorn*, 737 F.3d at 394.

requirement prohibits Generic Manufacturers from providing warnings or communications beyond those provided in their generic labels, including sending letters to physicians that brand manufacturers have not sent. *See Mensing*, 564 U.S. at 617; *In re Darvocet*, 756 F.3d at 935–36; *Strayhorn*, 737 F.3d at 391. Regardless of whatever form they take, state law claims that would require such warnings are preempted as a matter of law. *Mensing*, 564 U.S. at 617; *see also In re Darvocet*, 756 F.3d at 935–36; *Strayhorn*, 737 F.3d at 391.

This Court recently recognized this principle in the Tribal cases. There, the Court adopted Judge Ruiz's R&R recommendation that the failure-to-warn claims against generic manufacturers of opioid medicines be dismissed. The Court reasoned that requiring generic manufacturers "to send[] warnings that the Brand-Name Manufacturers had not sent . . . would violate[] the sameness principle." *Muscogee* R&R, ECF. No. 104 at 42.

C. Generic Manufacturers In This Case Did Not Market the Safety or Efficacy of Their Generic Medicines.

Plaintiffs have no evidence that any Generic Manufacturer made any false or misleading statements. Instead, the undisputed facts show the opposite: that many Generic Manufacturers have only ever sold generic medicines, and no Generic Manufacturer has promoted the safety and efficacy of its generic medicines anywhere, much less in Ohio. This is confirmed by testimony from: (a) Generic Manufacturers; (b) their experts; and (c) Plaintiffs' own experts.

Actavis Generic Defendants: On August 2016, Teva USA acquired Allergan plc's generic business in the form of the Actavis Generic Defendants.[12] The Actavis Generic Defendants have sold only generic medicines.[13] They have never promoted the safety, efficacy, or therapeutic value

[12] Ex. 4 (Declaration of David Myers, Associate Director of Marketing at Teva USA), at ¶ 3.
[13] Ex. 4 (Myers Declaration), at ¶ 4.

of their generic medicines, including generic opioids.[14] Although the Actavis Generic Defendants have used a small marketing team with a small marketing budget, their activities were limited to advertising the commercial availability of generic medicines.[15] Likewise, the Actavis Generic Defendants have never used continuing medical education ("CME"), speaker programs, or third parties to promote generic opioids.[16] As Andy Boyer, the former Senior Vice President of Actavis Sales and Marketing, put it: "We don't detail products . . . . These are not brands, these are generics. We offer up a price and we offer up a consistent supply in our supply chain and hopefully quality products . . . . There's no pushing, there's no detailing, there's nothing else there."[17]

Teva USA: Before 2011, Teva USA sold only generic opioid medicines.[18] It has never promoted the safety, efficacy, or therapeutic value of its generic medicines, including its generic opioids, to physicians or patients.[19] Similarly, Teva USA has never used CMEs, speaker programs, or third parties to promote its generic opioids.[20] Christine Baeder, Teva USA's Chief Operations Officer for U.S. Generics, testified that any marketing has been limited to providing information on pricing and "product availability."[21]

Mallinckrodt: Mallinckrodt's generics business does not promote the safety or efficacy of its generic opioid products to physicians or patients.[22] Mallinckrodt's generics business communicates, negotiates, and contracts with distributors, wholesalers, and national retail

[14] *See* Ex. 5 (Deposition of Douglas Boothe, former Executive VP and CEO of an Actavis Generic Defendant), at 146:21–147:10; Ex. 6 (Deposition of Michael Perfetto, former VP of Sales and Marketing of an Actavis Generic Defendant), at 315:11–21; Ex. 7 (Myers Deposition), at 83:6–11; Ex. 8 (Deposition of Jinping McCormick, former Marketing Manager of an Actavis Generic Defendant), 20:10–13, 112:20–114:24, 258:3–15.
[15] Ex. 9 (Deposition of Andrew Boyer, former Senior VP of Sales and Marketing of an Actavis Generic Defendant), at 346:9–17; Ex. 6 (Perfetto Deposition), at 315:22–316:2.
[16] Ex. 9 (Boyer Deposition), at 22:21–24, 125:9–129:21; Ex. 4, at ¶ 4 (Myers Declaration).
[17] *Id.* at 346:9–17.
[18] Ex. 12, at ¶ 3 (Declaration of Christine Baeder, Head of Generics at Teva USA).
[19] *See* Ex. 10 (Deposition of Christine Baeder), at 28:7–9, 40:9–13; Ex. 11 (Deposition of John Hassler, Senior VP and General Manager at Teva USA), at 108:8–13.
[20] Ex. 12, at ¶ 4 (Baeder Declaration).
[21] Ex. 10 (Baeder Deposition), at 417:2–5.
[22] Ex. 18 (Deposition of Kevin Vordestrasse), at 144:21–145:5.

pharmacy chains, not independent pharmacies or prescribers.[23] Mallinckrodt's generics business has no sales force that calls on physician offices.[24] Nor did it ever use key opinion leaders, speaker programs or third-party groups to promote the therapeutic benefits of its generic products.[25] And its "marketing" team provides product catalogs and company information—like availability and pricing—to distributors, wholesalers, and national retail pharmacy chains. [26]

Par Defendants: The Par Defendants manufacture generic opioid products and began selling Schedule II opioid medications in 2011.[27] Because the Par Defendants sell generic products, they do not market the clinical attributes of their products through physician detailing (as a branded company might) in the manner Plaintiffs allege forms the basis for their claims; rather, their sales communications are with parties (like bulk purchasers or distributors) that purchase products directly from the company and concern issues such as price and inventory.[28] There is no evidence that the Par Defendants have engaged in marketing or promotion of opioid medications regarding their safety, efficacy, or therapeutic value.[29] The Par Defendants also have not otherwise conducted events or presentations or hosted or supported conferences or educational programs about the safety, efficacy, or therapeutic value of opioids.[30] The Par Defendants' subsidiary Generics International (US), Inc. (and its subsidiaries) began selling Schedule II opioid medications after their formation in 2007. They also have not promoted the safety or efficacy of their generic opioid medications in the manner Plaintiffs allege forms the basis of their claims.[31]

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[23] Ex. 18 (Vorderstrasse Deposition), at 139:10–140:9.
[24] Ex. 19 (Deposition of Ginger Collier), at 253:13–19.
[25] Ex. 20 (Deposition of Lisa Cardetti), at 232:3–14.
[26] Ex. 18 (Vorderstrasse Deposition), at 139:10–23.
[27] Ex. 22 (PPI and PPCI's FRCP 30(b)(6) Responses, June 27, 2019), at p. 8.
[28] *Id*. at p. 10.
[29] *Id*. ("The sales personnel at Par, including legacy Qualitest personnel, have not engaged in the types of product-specific marketing or promotion alleged in the Complaint and have not been tasked with discussing efficacy, safety, or clinical profiles of Schedule II opioid medications.")
[30] *Id*. at p. 21.
[31] *Id*. at p. 10.

Endo Defendants: The Endo Defendants have sold various generic opioid medications, but have not promoted them to providers or otherwise engaged in promotional communications concerning their safety, efficacy, or therapeutic value. As the head of Endo's generics business explained: "There's no promotion[] in generics" and "[t]here's no representation to doctors."[32] He further testified that "marketing and generics is completely different" because it is limited to "the pricing" and ensuring accounts "know you have the product."[33]

Plaintiffs' Experts: Plaintiffs' own experts concede that Generic Manufacturers did not promote the safety or efficacy of their generic medicines. For example, Dr. Perri testified that generic manufacturers "do not promote the safety, efficacy, or benefits of their generic medications" and instead "focus[] on consistency of supply, pricing and quality of the products."[34] Likewise, Dr. Rosenthal testified that "[g]enerally, manufacturers will not detail physicians for generics. They may have other sales force activities that they do that relate to price, but individual physicians are not generally making a decision about one generic versus the other. That decision happens at the pharmacy."[35] Not surprisingly then, Plaintiffs have not identified a single misstatement made by any Generic Manufacturer about any of their generic opioid medications—much less one that was made to and misled a prescriber in Summit or Cuyahoga County.

Generic Manufacturers' Experts: Pain management, marketing, and health economic experts for Generic Manufacturers, including Drs. Michna, Chintagunta, Nicholson, and Rosenblatt, have confirmed that generic manufacturers do not market the safety and efficacy of opioids.[36] Dr. Chintagunta, for instance, has opined that "[t]o the extent generic medicines are

[32] Ex. 23 (Stevenson Deposition), at 70:13–14, 19.
[33] *Id*. at 70:7–10; 71:1–5.
[34] Ex. 13 (Deposition of Dr. Matthew Perri), at 547:15–548:8.
[35] Ex. 1 (Rosenthal Deposition), at 197:23–198:4.
[36] Ex. 14 (Michna Report), at ¶ 94; Ex. 15 (Chintagunta Report), at ¶¶ 23, 30, 41–50; Ex. 16 (Nicholson Report), at ¶¶ 44–49; Ex. 17 (Rosenblatt Report), at ¶¶ 67–68.

marketed at all, companies merely promote their commercial availability . . . there is no promotional spending for detailing or journal advertising for the safety, efficacy, or therapeutic value of the generic medicines."[37]

III. SUMMARY JUDGMENT SHOULD BE GRANTED.

Plaintiffs must present affirmative evidence to defeat summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). Plaintiffs cannot do so here.

A. Plaintiffs' False Marketing Claims (Counts I, III, and V-XI) Against Generic Manufacturers Necessarily Fail Because Plaintiffs Have No Evidence Of Any False Marketing As To Their Generic Medicines.[38]

Virtually all of Plaintiffs' claims against Generic Manufacturers rest upon allegations of false marketing.[39] As explained above, the undisputed facts and expert testimony show that Generic Manufacturers have never promoted the safety and efficacy of their generic opioids. Plaintiffs have no evidence to the contrary. Nor is there any evidence that any Generic Manufacturer sponsored any third-party publications or programs with respect to generic opioid medicines, much less controlled the content of those publications. For this reason alone, summary judgment is appropriate. *See, e.g.*, *In re Darvocet*, 756 F.3d at 925 (rejecting claims based on theory that "Generic Manufacturers wrongfully marketed" their generic medicines).

Of course, because Plaintiffs cannot show any false marketing of generics, they have no evidence to support the other basic elements of their claims—causation or a cognizable injury. Plaintiffs simply have no evidence that any physician was misled by any such marketing into writing a prescription that caused harm to Plaintiffs. Thus, summary judgment is appropriate.

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[37] Ex. 17 (Chintagunta Report), at ¶ 46.

[38] The Actavis Generic Defendants are not defendants with respect to the RICO and OCPA false marketing claims in Counts I and III of Plaintiffs' Third Amended Complaints.

[39] *See* Summit TAC ¶ 879 (Count I), ¶ 946 (Count III), ¶ 990 (Count V), ¶ 1001 (Count VI), ¶ 1047 (Count VII), ¶ 1074 (Count VIII), ¶ 1094 (Count IX), ¶ 1110 (Count X), ¶ 1125 (Count XI); Cuyahoga TAC ¶ 923 (Count I), ¶ 988 (Count III), ¶ 1031 (Count V), ¶ 1049 (Count VI), ¶ 1090 (Count VII), ¶ 1117 (Count VIII), ¶ 1137 (Count IX), ¶ 1152 (Count X), ¶ 1167 (Count XI).

B. Any Claims Against Generic Manufacturers Based Upon A Failure To Warn Theory Are Preempted.

To the extent Plaintiffs assert that their false marketing claims against Generic Manufacturers are based on a failure-to-warn or other omission-based theory, the claims fail—regardless of how they are styled—for a separate fundamental reason: they are preempted under *Mensing* and Sixth Circuit precedent.

In *Mensing*, plaintiffs alleged state-law failure-to-warn, fraud, and negligent misrepresentation claims against generic drug manufacturers based on the manufacturers' alleged failure to provide adequate warning labels. 564 U.S. at 608–09. The Supreme Court recognized that the plaintiffs' claims, if valid, would require the use of different labeling. *Id.* at 612. Federal law, however, did not allow the defendants to make the change plaintiffs argued was necessary to satisfy state law. As a result, the Supreme Court found the claims preempted. *Id.* at 618; *see also Bartlett*, 570 U.S. at 490 (applying rule); *Muscogree* R&R, at 42 (same).

Plaintiffs cannot sidestep this controlling law. Regardless of how Plaintiffs style their state law claims, Plaintiffs simply cannot bring failure-to-warn or failure-to-communicate claims against Generic Manufacturers. Any such claims still would require Generic Manufacturers to change their labels or otherwise provide different safety warnings regarding the risks posed by unidentified opioid medicines to avoid liability—an impossible request in light of the federal "sameness" requirements. *Id.*; *see also In re Darvocet*, 756 F.3d at 935–36 (rejecting fraud and other claims against generic manufacturer as preempted failure-to-warn claims); *Strayhorn*, 737 F.3d at 391 (applying rule and dismissing fourteen state law claims, including civil conspiracy).[40]

[40] To the extent Plaintiffs may try to argue that evidence of Generic Manufacturers' participation in a civil conspiracy makes them liable for false marketing committed by others, this argument has been squarely rejected by the Sixth Circuit. In dismissing civil conspiracy claims against a generic manufacturer, the Sixth Circuit held that "even if the civil-conspiracy claim was adequately supported by factual allegations, the essence of such a claim is that there was a tacit agreement between the manufacturers not to warn, or not to adequately warn, about the dangers of [a generic

Nor can Plaintiffs avoid preemption by arguing that its state law claims are based upon the theory that Generic Manufacturers should have sent letters or other communications to physicians that further communicated risk information about opioids to counteract any other allegedly false promotion in the marketplace. The Supreme Court, the Sixth Circuit, and every other federal court that has addressed this issue have made clear that generic manufacturers are not permitted to communicate ***any warnings*** beyond a generic label if brand-name manufacturers have not already sent such a communication, because doing so "would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly 'misleading.'" *Mensing*, 564 U.S. at 615 (claims that generic drug manufacturers failed to send "Dear Doctor" Letters to healthcare professionals regarding generic medicine's risks were preempted because they would violate federal law); *see also McDaniel*, 893 F.3d at 944–48 (failure-to-warn claims based upon alleged failure to provide Medication Guide are preempted); *Muscogee* R&R, at 42 (same).[41]

C. Plaintiffs' Theory That Generic Manufacturers Can Be Held Liable For Alleged Fraud By Others Fails As A Matter Of Law.

Generic Manufacturers also cannot be held liable merely for selling their FDA-approved medicines in an opioid market that was allegedly created by the fraudulent marketing of others. This theory fails as a matter of law for multiple independent reasons.

First, as a matter of basic tort law, Generic Manufacturers cannot be held liable for the alleged fraudulent acts of others. As explained above, Generic Manufacturers made no false or

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medicine]—a failure-to-warn claim that, for the reasons already discussed, is preempted under *Mensing*." *Strayhorn*, 737 F.3d at 400. In addition to being preempted, Plaintiffs' civil conspiracy claims also fail for the independent reasons stated in Manufacturers' Joint Motion for Summary Judgment On Plaintiffs' RICO, OCPA, And Conspiracy Claims—namely, that there is simply no evidence to support a conspiracy claim against Generic Manufacturers, including any agreement to engage in any false marketing or any other improper conduct.

[41] The same analysis applies to the RICO claims. Although preemption involves "the question [of] whether state law is preempted by a federal statute," preemption principles are "instructive" in cases "concern[ing] the alleged preclusion of a cause of action under one federal statute" (here, RICO) "by the provisions of another federal statute" (here, the FDCA). *Pom Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014). Generic Manufacturers cannot be penalized through a RICO claim for doing what the FDCA requires.

misleading statements. And even if Plaintiffs could show that they had knowledge about the alleged false marketing of other manufacturers, that is legally insufficient to impose liability on Generic Manufacturers absent some duty to disclose to Plaintiffs. *See, e.g.*, *Lee v. Countrywide Home Loans, Inc.*, 692 F.3d 442, 450 (6th Cir. 2012) (recognizing that under Ohio law, "[a]bsent a duty to disclose, mere concealment of a material fact, on its own, does not constitute fraud"). Indeed, even where defendants "directly benefit and knowingly participate in a transaction tainted with fraud or deceit," they are subject to liability for fraud only if they are "under a duty to disclose their knowledge." *Moore v. Burt*, 645 N.E.2d 749, 758 (Ohio Ct. App. 1994) (citation omitted).

Second, this case does not present one of the narrow instances where Ohio law or RICO imposes a duty on Generic Manufactures to disclose additional warnings or communications.[42] Generic Manufacturers have no fiduciary relationship with Plaintiffs or prescribers, there are no statements made by Generic Manufacturers about their opioid medicines that require correction, and there are no other unique circumstances triggering a duty to disclose. And even if state or federal law did impose a duty to disclose additional warnings about generic medicines on Generic Manufacturers, it would violate the duty of sameness rule; therefore, it would be preempted for the reasons discussed above. *See Mensing*, 564 U.S. at 615; *McDaniel*, 893 F.3d at 944–48 .

Third, Plaintiffs cannot avoid preemption by arguing that Generic Manufacturers are liable because they should have refrained from selling FDA-approved drugs altogether unless they corrected alleged misimpressions by others about opioids. The Supreme Court and the Sixth Circuit have both rejected this "stop-selling" theory of avoiding liability. *See Bartlett*, 570 U.S. at

[42] *See, e.g.*, *Chiarella v. United States*, 445 U.S. 222, 228 (1980) (holding that a "duty to disclose arises when one party has information 'that the other [party] is entitled to know because of a fiduciary or other similar relation of trust and confidence between them.'") (alteration in original) (citation omitted); *Miles v. Perpetual Sav. & Loan Co.*, 58 Ohio St. 2d 97, 100 (1979) (holding that "[o]ne who makes a representation that is true when made is under a duty to correct that statement if it becomes erroneous or is discovered to have been false before the transaction is consummated"); *Williams v. Duke Energy Int'l, Inc.*, 681 F.3d 788, 802 (6th Cir. 2012) (same for RICO).

488 ("We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence."); *In re Darvocet*, 756 F.3d at 925 (citing with approval that the "*Barlett* court reject[ed] the 'stop selling' theory, namely that a generic manufacturer could have avoided the conflict between state and federal law by refraining from selling the drug"). Plaintiffs cannot hold Generic Manufacturers liable for doing exactly what the FDA allows. Nor does impossibility preemption allow Plaintiffs to force Generic Manufacturers to cease conduct that is consistent with federal law. Such a theory reeks of "incoherence." *Bartlett*, 570 U.S. at 488.

IV. CONCLUSION

For the foregoing reasons, the Court should grant Generic Manufacturers' motion for summary judgment on all false marketing claims.

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on June 27, 2019, the foregoing was filed using the Court's CM/ECF filing system and will be served via the Court's CM/ECF filing system on all attorneys of record.

/s/ Steven A. Reed
Steven A. Reed